

John Hellerstedt, M.D.

Commissioner

December 27, 2020

Nursing Facility Administrator:

I am writing to alert you of the availability of two types of monoclonal antibody infusions that have potential benefits to certain patients who have tested positive for the virus that causes COVID-19.

We urge leaders in your facility's administration to inform the medical director and physicians of record of these therapeutic modalities, their known potential benefits and known potential risks, as well as how to obtain these therapies for residents of your facilities.

One of the available products is bamlanivimab, which is manufactured by Eli Lilly. The other product is a combination of two monoclonal antibodies—casirivimab and imdevimab—and is manufactured by Regeneron. Each product is covered by an Emergency Use Authorization (EUA) issued by the federal Food and Drug Administration. Prospective patients must fit the criteria of the EUA. A link to the EUA and many other clinical resources related to these products is provided in the attachment to this letter and email.

Administration of either of these products is a medical decision and requires a physician's order. We urge you to notify your medical directors and your residents' treating physicians of these new and potentially beneficial therapies. Please share the clinical information we have provided with all parties you deem appropriate.

The medical data is clear that these therapies can prevent hospital admissions in some patients who meet the clinical criteria documented in the respective EUAs.

Texas has received a significant supply of these products. The state can provide you with these therapeutic agents for patients whose physicians have approved their use.

To facilitate urgent delivery of either of these monoclonal antibody products, or if you have any questions, contact your facility's Texas Health and Human Services Commission (HHSC) regional director or director of survey operations. If you would like your facility to be considered for regular shipments in the future, please also complete this survey.

Sincerely,

John Hellerstedt, MD

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Attachment

Resources

• Bamlanivimab (Lilly)

- o Emergency Use Authorization (EUA) for emergency use of bamlanivimab
- o Bamlanivimab Fact Sheet for Healthcare Providers
- Bamlanivimab Fact Sheet for Patients and Caregivers
- o FDA Frequently Asked Questions on the EUA for Bamlanivimab
- o <u>Lilly bamlanivimab information</u>
- o Lilly Bamlanivimab Antibody Playbook
- o Bamlanivimab Pocket Resource Card
- o Bamlanivimab Overview, Allocation, and Distribution

Casirivimab/Imdevimab (Regeneron)

- Emergency Use Authorization (EUA) for emergency use of casirivimab and imdevimab
- FDA Frequently Asked Questions on the Emergency Use Authorization of Casirivimab + Imdevimab
- <u>Casirivimab/Imdevimab Fact Sheet for U.S. Health Care Providers</u> (English)
- Important Prescribing Information: A Letter from Regeneron to Healthcare Providers on Preventing Medication Errors
- <u>Casirivimab/Imdevimab Fact Sheet for Patients and Caregivers (English)</u>
- o Regeneron casirivimab/imdevimab information
- o Regeneron casirivimab/imdevimab guidebook
- Overview, Allocation & Distribution (casirivimab/imdevimab)

Billing and Coding

- o Centers for Medicare and Medicaid Services Provider Toolkit
- COVID-19 Frequently Asked Questions on Medicare Fee-for-Service Billing
- CMS Monoclonal Antibody COVID-19 Infusion